UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA
ex rel.
CONSTANCE A. CONRAD

C. A. No. 02-CV-11738-RWZ

Plaintiffs,

v.

ABBOTT LABORATORIES, INC., *et al*.

Defendants.
_____/

RELATOR'S OPPOSITION TO THE CONSOLIDATED DEFENDANTS' MOTION TO DISMISS

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Introduction

In 2002, the Relator, Constance Conrad, blew the whistle on an extensive fraud involving more than twenty pharmaceutical companies. She alleges that these companies deceived Medicaid into paying more than half a billion dollars for their products by fraudulently representing the products as Medicaid eligible. After years of investigation, the U.S. Attorney's Office intervened and reached settlements with five of the companies Ms. Conrad identified. Just the civil portion of those settlements totals more than $85 million. The government has now intervened against a sixth defendant, Healthpoint, seeking at least $90 million more in damages, for claims based on the very same fraudulent scheme Ms. Conrad alleges against the Consolidated Defendants. In addition, the attorneys general of Massachusetts, Virginia, and Florida have intervened against Healthpoint to seek recoveries for their respective states based upon the misconduct Ms. Conrad identified as well.

The Consolidated Defendants propose five grounds upon which they seek to dismiss Ms. Conrad's Complaint. First, they claim that the Complaint should be dismissed because of the public disclosure bar, citing massive agency data files, and the absence of certain information in unverified directories it claims are "administrative reports." No court, however, has found that information contained in such repositories qualify as administrative reports for purposes of the public disclosure bar, or that the absence of information can be a disclosure. Nor has any court dismissed a case on this basis as a so-called "parasitic" action where the government has intervened against several defendants, and obtained eight figure recoveries.

Second, Defendants claim that some of their Non-Drug products and unapproved drugs *could* be covered by the states and therefore the claims for reimbursement may not be false. Yet Defendants cite no statutory provisions, or case law, that authorize federal Medicaid reimbursement for their products.

Next, they argue that the Relator's claims are not pled with sufficient specificity under Rule 9(b). But they rely on the pleading standard applicable to false claims made directly by a defendant, ignoring the different standard applicable to the indirect claims alleged here, a standard easily met in this case.

Finally, Defendants argue that the Complaint cites a version of the law which was amended after the initial Complaint was filed, and that some claims are time barred because the limitations period runs from the date of unsealing. The first issue is clerical, the second a notion rejected by courts in jurisdictions across the country, including here. The Consolidated Defendants' motion should be denied in its entirety.

I. The Relator's Claims Are Not Subject To the Public Disclosure Bar.

The public disclosure bar deprives the court of jurisdiction only when the relator's claims are based upon "public disclosure of allegations or transactions" from a qualifying source under the statute. 31 U.S.C. § 3730(e)(4)(A). To give rise to the public disclosure bar, the "allegations or transactions" at issue must be disclosed:

> (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;
>
> (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or
>
> (iii) from the news media.

31 U.S.C. § 3730(e)(4).

The First Circuit has taken a narrow view of these "qualifying sources" emphasizing that they are both exclusive and exhaustive. "[The FCA] does not deny jurisdiction over actions based on disclosures other than those specified." *United States of America ex rel. LeBlanc v. Raytheon Co., Inc.,* 913 F.2d 17, 20 (1st Cir. 1990). Information that is outside the parameters of a "public disclosure" under the statute does not implicate the bar.

Defendants do not allege that there has been any public disclosure made via "hearing," "investigation," "audit," or the "news media." They contend solely that Ms. Conrad's allegations are substantially similar to allegations and transactions disclosed in alleged "administrative reports." Defendants' Memorandum ("Def. Mem.") at 13, 20-21.

The Consolidated Defendants identify five specific "administrative reports" that purportedly contain such "substantially similar allegations or transactions":

1. CMS's drug product data "reports";
2. CMS's state drug utilization data "reports";
3. FDA's "Orange Book";
4. FDA's national drug code directory; and
5. FDA Federal Register DESI notices and new drug rulings.

Def. Mem. 9 – 12, 13.

CMS does not call the product data and utilization data files "reports." The Defendants just added that word to these two CMS digital files. Such "unadorned data

files"[2] are ubiquitous in our digital age, and cannot sensibly be identified as the "administrative reports" the public disclosure bar deems a qualifying source. Similarly, the NDC Directory is just that, a directory, not a report. Defendants curiously cite FDA's Orange Book for its *omission* of their products, not for any affirmative disclosure. Finally, although FDA Register notices may be deemed "administrative reports" for some purposes, here their content does not disclose the essential elements of the fraud Ms. Conrad alleges of Defendants.

A. Defendants' Interpretation Of The Public Disclosure Bar Subverts Its Purpose Of Encouraging Productive *Qui Tam* Actions.

Defendants correctly note that the purpose of the public disclosure bar is to prevent carpetbagging by "opportunistic" relators who bring nothing of value to a case, but simply repackage allegations already in the public domain. Def. Mem. at 14. *See United States ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645, 651 (D.C. Cir. 1994)(current FCA "represent[s] … congressional effort to reconcile avoidance of parasitism and encouragement of legitimate citizen enforcement actions…."). To that end, its "goal [is] avoiding suits that merely drain the public fisc…." *Id.*, at 657. But this suit has *enhanced* the public fisc, with the promise of more to come if it is not dismissed. Seeking that dismissal, Defendants nevertheless contend that Ms. Conrad is the type of "opportunistic" plaintiff this Court should not hear. Def. Mem. at 14.

As noted, the government has already recovered $85 million through settlements of the claims Ms. Conrad brought to its attention, with the prospect of another $90

[2] As Defendants accurately describe them. Def. Mem. at 10.

million from its proceeding against Healthpoint.[3] *See* Forest settlement ($42.5 million), Schwarz settlement ($22 million), KV/Ethex settlement ($17 million), and Eon settlement ($3.5 million), described in the Department of Justice press releases attached as Exhibit A.

The docket itself belies the Defendants' attempt to portray the very same claims that enabled these recoveries as somehow "opportunistic" because made against them rather than the pharmas the government has settled with. If the essential elements of the alleged fraud were so easily discoverable from "qualifying sources" that "anyone" could have filed this case, Def. Mem. at 17-25, how is it that the government recovered nothing for these types of claims before Ms. Conrad filed her Complaint, has only recovered money within the confines of this case, and has chosen to pay Ms. Conrad a percentage of the recovery for her exposure of the fraud?

The fact is, the government had no ongoing investigation concerning Ms. Conrad's allegations, or even of this scheme in general, and there had been no public exposure of such allegations until Relator's complaint was first unsealed. As the First Circuit observed: "When the material elements of a fraud are already in the public domain, the government has *no need for a relator to bring the matter to its attention*…." *United States ex rel. Ondis v. City of Woonsocket,* 587 F.3d 49, 58 (1st Cir. 2009)(emphasis added). Here, the proceedings to date demonstrate that the government did need Ms.

[3] *See* Complaint of the United States, Mar. 31, 2011, [Docket No. 217]; Motion for Leave to Intervene of Commonwealth of Massachusetts, May 25, 2011, [Docket No. 225]; State of Florida's Motion to Intervene as a Matter of Right or in the Alternative Florida's Permissive Intervention, Nov. 16, 2011, [Docket No. 295]; Commonwealth of Virginia's Motion for Leave to Intervene, Jan. 27, 2012, [Docket No. 355].

Conrad to bring this matter to its attention, and its settlements expressly acknowledge her valuable contribution to its recoveries.

The purpose of the public disclosure bar is not to give defendants the right to commit fraud as long as some aspect of their misconduct is publicly discoverable, rather it is to establish "the golden mean between adequate incentives for whistle-blowing insiders with *genuinely valuable information* and discouragement of opportunistic plaintiffs *who have no significant information* to contribute...." *United States ex. rel. O'Keefe v. Sverdup Corp.*, 131 F. Supp. 2d 87, 91 (D. Mass. 2001)(emphasis added).

It is a strange notion that Defendants advance – that the public disclosure bar, a provision designed to protect the government from "free riding opportunists,"[4] should be interpreted instead to protect *them* from liability and deprive the government of the additional recoveries, *from them*, that Ms. Conrad seeks. The FCA cannot be interpreted to provide such an "absurd result." *Seal 1 v. Seal A*, 255 F. 3rd 1154, 1161 (9th Cir. 2001).

1. The Public Disclosure Bar's Legislative History Confirms Its Goal Of Encouraging Suits Like This One.

The public disclosure bar is best understood in the context of the *qui tam* statute's evolution. *Springfield Terminal Ry. Co.,* 14 F.3d at 649 ("the past serves as prologue; some familiarity with [its] tortuous, wending history is critical to an understanding of the [FCA].")

As first enacted, the FCA allowed relators to bring suit even though they provided no information of value to the government. In scores of purportedly

[4] *See Ondis,* 587 F.3d at 53 and *United States ex rel. Poteet v. Bahler Med., Inc.*, 619 F.3d 104, 107 (1st Cir. 2010).

"parasitical suits"[5] relators simply copied government files and indictments and brought claims based on them. In 1943, the Supreme Court ruled that even a relator who allegedly contributed nothing to discovery of a crime and essentially copied allegations from a criminal fraud indictment could maintain a *qui tam* suit. *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 546, 63 S.Ct. 379, 87 L.Ed. 443 (1943).

In response, Congress amended the FCA to bar suits based upon evidence or information the government already had. 31 U.S.C. § 3730(b)(4) (1982) (superseded). This government knowledge bar killed the golden goose, so in 1986 Congress replaced it with the current public disclosure provision, designed to strike a balance between the two extremes, to "discourag[e] 'parasitic' or 'free-loading' qui tam suits while also encouraging productive private enforcement suits." *In re Pharm. Indus. Average Wholesale Price Litig.*, 538 F. Supp. 2d 367, 376 (D. Mass. 2008) quoting *United States ex rel. Rost v. Pfizer*, 507 F.3d 720, 727 (1st Cir. 2007). It is in this context and with this balance in mind that courts must apply the current bar to meet the provision's legislative goals.

2. This Case Is The Antithesis Of A Parasitic Suit.

The legislative history of the current public disclosure bar reveals "a sense that fraud against the Government was apparently so rampant and difficult to identify that the Government *could use all the help it could get from private citizens*." *United States ex rel. LaValley v. First Nat'l Bank*, 707 F. Supp. 1351, 1355 (D. Mass. 1988)(emphasis added).

[5] *See, e.g., United States ex. rel. Pettis v. Morrisson-Knudsen Co.,* 577 F.2d 668, 671 (9th Cir. 1978)(*citing United States v. Pittman,* 151 F.2d 851, 854 (5th Cir. 1945), *cert. denied,* 328 U.S. 843, 66 S.Ct. 1022, 90 L.Ed. 1617 (1946).

Ms. Conrad's suit has certainly provided the government with substantial help on that score, a fact which Defendants studiously ignore.

Far from simply "repastinating previously disclosed badges of fraud," *United States ex rel. Poteet v. Bahler Med., Inc.,* 619 F.3d 104, 112 (1st Cir. 2010) *quoting Ondis,* 587 F.3d at 53, her efforts are based on painstaking research conducted over several years. The investigatory work Ms. Conrad did, much like archaeology, unearths *information*, which must be distilled and analyzed to produce the disclosure memoranda and complaints which the government has here relied upon. This investigation and vetting process is as distinct from the parasitic copying of "administrative reports" as original work is from plagiarism. This is information the government itself has not been able to discover in the first place, much less compile into a lawsuit which provides chapter and verse proof of the Defendants' scheme.

B. The Cases Defendants Rely Upon Confirm That No Qualifying Public Disclosure Exists Here.

In nearly all of the cases Defendants cite the relators relied variously on the government's response to a FOIA request, court documents in a previously filed FCA cases, other litigation, or newspaper articles, all clear examples of prior public disclosures. The lack of public information regarding Ms. Conrad's allegations here, by contrast, demonstrates the flaw in Defendants' argument. A review of these cases is instructive.

Ondis, 587 F.3d at 52, involved disclosures in a FOIA response and in newspaper articles which the relator conceded were publicly disclosed. *Id.,* at 54.The First Circuit

ruled that an agency response to a FOIA request also constitutes a public disclosure for purposes of § 3730(e)(4)(A), because "a FOIA response is a report, at least in the sense that it constitutes an official statement concerning the results of the agency's search of its files." *Id.*, at 56. The relator's case was barred because the two public disclosures, the newspaper report and FOIA response, placed "all the essential elements of the alleged fraud" clearly in the public domain. *Id.,* at 55.

Likewise, in *In re AWP Litig.,* 538 F. Supp. 2d 313 (D. Mass. 2008), Judge Saris dismissed claims in an average wholesale price *qui tam* based on certain forms of fraud which were publicly disclosed in two prior AWP complaints filed against the defendant's parent company. Other fraud allegations, based on other schemes, were not publicly disclosed and could proceed. *Id.,* at 383, 385. Similarly, in *United States ex rel. Settlemire v. District of Columbia,* 198 F.3d 913, 919 (D.C. Cir. 1999), the relator's claim that the District of Columbia used federal funds improperly was barred because it was based on statements made by D.C. officials in a congressional hearing, that they believed that their use of the funds was unrestricted.

In this case, there was no FOIA response, no prior *qui tam* action, no prior litigation of any kind, no newspaper articles, no congressional testimony. And, significantly, none of the cases Defendants cite resulted in government intervention, recovery, or the payment of a relator's share, as happened here. The public disclosure bar is inapplicable.

C. The Sources Defendants Cite Confirm That There Was No Public Disclosure – They Are Not Qualifying Sources And They Contain Neither Allegations Of Fraud Nor The Essential Elements of Fraudulent Transactions.

Determining whether the public disclosure bar deprives a court of jurisdiction involves a three-part inquiry: "(1) whether there has been a prior, public disclosure of fraud; (2) whether that prior disclosure of fraud emanated from a source specified in the statute's public disclosure provision; and (3) whether the relator's *qui tam* action is 'based upon' that prior disclosure of fraud." *Poteet,* 619 F.3d at 109. If the answer to even *one* of these inquiries is no, then the public disclosure bar does not apply. *Id*. Here, the answer to all three is no.

1. There Was No Prior Public Disclosure Of Fraud: The Information Defendants Assert Was Publicly Available Does Not Reveal The "Vital Ingredients" Of Any Fraudulent Transaction.

A prior public disclosure of fraud occurs "when the *essential elements* exposing the particular transaction as fraudulent find their way into the public domain." *Poteet,* 619 F.3d at 110 (emphasis added), quoting *Ondis*, 587 F.3d at 54. Such a disclosure must contain either "(1) a direct allegation of fraud, or (2) both a misrepresented state of facts and a true state of facts so that the listener or reader may infer fraud." *Poteet*, 619 F.3d at 110. Here, Defendants do not argue that there were any previously disclosed *direct allegations* of fraud. Therefore they must show that the essential elements of fraudulent transactions were sufficiently disclosed so as to raise an inference of fraud. They cannot.

The FCA bars suits based on publicly disclosed "allegations or transactions, *not information*." *Springfield Terminal Ry. Co.,* 14 F.3d at 653 (criticizing "[c]ourts [which] speak loosely of barring a *qui tam* suit because it is based on 'publicly disclosed

information.")(citations omitted). Defendants merely point to five general information sources, which collectively contain enormous quantities of data, and ask this Court to find that these sources, together with what these sources lack, disclose "the vital ingredients to a fraudulent transaction, exist[ing] in the public eye." *Id*., at 657. Those vital ingredients are not disclosed in the information these repositories contain.

In addition, the public disclosure bar contemplates a situation where "the essential elements exposing the *particular transaction as fraudulent* find their way into the public domain." Def. Mem. at 14, citing *Poteet*, 619 F.3d at 110, quoting *Ondis,* 587 F.3d at 54. Prior to the filing of this action, there was no disclosure in any of the five places Defendants characterize as "qualifying sources" which contained the essential elements "exposing [a] particular *transaction*" as fraudulent.

Defendants cite no disclosures of fraudulent transactions involving reimbursement for products that were not Covered Outpatient Drugs; providers submitting false claims for these products to state Medicaid programs; or states submitting false reports to CMS. Without these essential elements, there can be no inference of fraud. The public disclosure bar is not triggered where the public disclosures are "not adequate to set the government squarely on the trail of fraud." *In re AWP Litig*., 538 F. Supp. 2d at 387 (citations omitted).

Nor do any of the sources Defendants cite: (1) suggest any fraud or false representations related to the Medicaid Rebate Program; (2) imply that any of the drugs or products in the Medicaid Rebate Program are not Covered Outpatient Drugs; (3) suggest that there are any false representations contained in the states' Quarterly

Reports to CMS; (4) imply that there was even a risk of fraudulent or false claims being submitted to the Medicaid Rebate Program; or (5) suggest that there was even a risk of fraud or false claims being submitted for non Covered Outpatient Drug products. These are the essential allegations that form the basis for the Complaint.

Nothing in the information Defendants cite raises an inference of fraud. Courts decline to read § 3730(e)(4) so broadly as to assume that the reader will construct a theory of a fraudulent scheme from facially valid or innocuous transactions. *See Springfield Terminal Ry. Co.*, 14 F.3d at 655 (pay vouchers and telephone records from earlier action did not publicly disclose essential elements of claim that arbitrator submitted false expense bills to government; vouchers and records provided no inherent indication of fraud); *United States ex rel. Rabushka v. Crane Co.*, 40 F.3d 1509, 1512-14 (8th Cir. 1994)(no inference of pension fraud contained in reports describing defendant's ostensibly legitimate transactions); *United States ex rel. Pogue v. American Healthcorp, Inc.*, 977 F. Supp. 1329 (M.D. Tenn. 1997)(disclosure of facially valid transactions in SEC reports did not disclose allegations or transactions underlying *qui tam* complaint). As the Eighth Circuit emphasized, construing the disclosure bar too broadly is unsupported by the purposes of the Act and "would choke off the efforts of qui tam relators." *Rabushka*, 40 F.3d at 1514. To be a public disclosure for purposes of the Act "the information put in the public domain [must] present so clear or substantial an indication of foul play as to qualify as either an allegation of fraud or a fraudulent transaction." *Id*.

In cases where the essential elements underlying the fraud claim are found to

have been publicly disclosed, the disclosures contain a clear implication that fraud has taken place. *See, e.g., United States ex rel. Findley v. FPC Boron Employees' Club*, 105 F.3d 675, 687 (D.C. Cir. 1997)(public disclosures "specifically identify the nature of the fraud--illegal retention of monies owed to the government and unauthorized administrative approval of the practice--as well as the federal employee actors engaged in the allegedly fraudulent activity"); *United States ex rel. Fine v. Sandia Corp.*, 70 F.3d 568, 572 (10th Cir. 1995)(public disclosure of the same fraud in prior law suit rendered easily identifiable the transactions identified in relator's complaint, and "set the government squarely on the trail of the alleged fraud without [the relator's] assistance"). The alleged disclosures Defendants rely upon do not reveal, imply or even suggest fraud.

Disclosures that merely reveal information, as opposed to fraudulent "allegations or transactions," do not invoke the public disclosure bar. *Springfield Terminal Ry. Co.,* 14 F.3d at 653; *United States ex rel. Purdue Pharma LP*, 582 F. Supp. 2d 766, 770 (W.D. Va. 2008); *United States ex rel. Rabushka v. Crane Co.*, 40 F.3d 1509, 1512-14 (8th Cir. 1994).

2. CMS Data Files Are Not Administrative Reports.

Defendants contend that the "misrepresented facts," that their unapproved and Non-Drug products *were* Covered Outpatient Drugs eligible for Medicaid reimbursement, entered the public domain through two alleged public disclosures. These are, according to Defendants: (1) the rebate drug product data file, which contains a list of active drugs reported to CMS by drug manufacturers participating in

the Medicaid Rebate Program, and (2) the state utilization data file, which contains data regarding drugs paid for by State Medicaid agencies. *See* Defendants' Exhibits 4 and 8.

Perhaps to buttress their contention that these information sources are "administrative reports," Defendants added the word "reports" after the descriptor "data file" when referring to these files in their "Glossary" and throughout their brief. *See, e.g.,* Def. Mem. at xiii, xvi, 13, 20-21. But simply calling them reports does not make them so. CMS has never identified these information sources, which are available for download from the Drug Rebate Program Data section of the CMS website, as anything but mere "data" files.[8] Each of the files contains thousands of lines of data, most of which is unrelated to the claims raised in the Complaint. Defendants elsewhere admit that these are simply "unadorned" data tables. Def. Mem. at 10. These files in no way give rise to an inference of any fraudulent transactions, nor are they "qualifying sources," in that data tables cannot be sensibly called "administrative reports" as defined by the FCA.

None of the cases Defendants cite support the argument that a raw data file is an "administrative report." In fact they suggest the opposite. *Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. __, 130 S. Ct. 1396 (2010) is illustrative. It involved a *qui tam* alleging fraud in county contracts with the USDA to cleanup flooded areas. *Id.*, at 1398. County officials investigated allegations of fraud, and hired an accounting firm to perform an audit which revealed potential

[8] http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Medicaid-Drug-Rebate-Program-Data.html

irregularities. *Id.,* at 1400. A state agency subsequently issued a second report identifying similar problems. *Id.* Finally, the USDA's Inspector General issued a *third report* that contained additional findings. *Id.* Each of these was found to be an "administrative report" under the public disclosure provision. *Id.*, at 1411.

United States ex rel. Mistick PBT v. Housing Authority of City of Pittsburgh, 186 F.3d 376 (3rd Cir. 1999) alleged that the defendants made false claims to HUD for lead paint abatement at housing projects. The relator made a FOIA request to HUD for information regarding the claims. *Id.,* at 381. Citing the dictionary definitions of a "report," the Third Circuit held that a response to a FOIA request, which included the alleged false claims, was an administrative report because it provided information and notification "regarding the *results of the agency's search for the requested documents* and constitutes *an official and formal statement concerning those results*." *Id.,* 383-384 (emphasis added).

In *United States ex rel. Kirk v. Schindler Elevator*, 563 U.S. __, 131 S. Ct. 1885, 1892 (2011), the Supreme Court similarly found that a FOIA response by DOL which reported the results of the agency's search of its records was an administrative report. *Id.,* at 1890. The Court cited the dictionary definitions of "report" as well as the agency's obligations when a FOIA request is received, to respond in writing, provide reasons for its response, the persons involved, reasons for any denial, and notification if any records cannot be located. *Id.,* at 1893. Such a response "plainly is 'something that gives information,' a 'notification,' and an 'official or formal statement of facts.'" *Id.*

Notably, each of these cases involved an actual *report* by a government agency – either an audit report in *Graham,* or a review of the agency's records, and the issuance of a written response with the results of that review. Defendants cite no case, nor is there one, which finds that a digital file with thousands of lines of data regarding thousands of products qualifies as an administrative report.

The term administrative report contemplates both synopsis and analysis. The public disclosure bar is a limited and exclusive provision. *LeBlanc*, 913 F.2d at 20. This part of the statute was amended in 1986 when data files were contained primarily in mainframes. In 2012 data files are ubiquitous. Congress could not have foreseen this technological revolution and therefore could not have meant to turn the contents of every hard drive into an "administrative report." To paraphrase the First Circuit: "[t]he reading urged here … is overbroad so as to prohibit cases that are 'productive private enforcement suits.' Thus, just as we eschewed reading an exclusion in *Rost* that did not have textual support and resulted in discouraging 'productive private enforcement,' we similarly decline to do so here." *United States ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 579 F.3d 13, 27 (1st Cir. 2009). This Court should do the same.

3. The Alleged "True State Of Facts," That Defendants' Products Were Ineligible For Reimbursement, Was Not Publicly Disclosed: The Absence Of Information Is Not A Disclosure.

Defendants next contend that the alleged true state of facts, that their products were *not* Covered Outpatient Drugs, was publicly disclosed through multiple sources reflecting the FDA approved status of drugs: FDA's Orange Book, the NDC Directory,

the "DESI-2 List," the FDA New Drug Notices, and DESI Notices published in the Federal Register. *See* Defendants' Appendix A.

According to Defendants, anyone could have cross referenced the thousands of drug products listed in the Orange Book with multiple sources that enable the investigator to "follow the ingredients," and then filed a *qui tam*. Def. Mem. at 20-21. While the Orange Book contains information on over 15,000 substances, it does not contain a list of drugs or Non-Drugs that do not meet the definition of a Covered Outpatient Drug. Defendants cite no case, nor is there one, holding that the *absence of information* in a compendium constitutes a public disclosure of the essential elements of a fraudulent transaction.

Defendants portray the NDC Directory as a qualifying disclosure of "drugs on file with the FDA." Def. Mem. at 13. But the NDC Directory only contains unverified information provided by manufacturers and labelers themselves, and contains no information relevant to proving the essential elements of the Relator's claims. The introduction to the NDC directory makes this clear:

> Inclusion of information in the NDC Directory does not indicate that FDA has verified the information provided. The content of each NDC Directory entry is the responsibility of the labeler submitting the SPL file.
>
> Neither inclusion in the NDC Directory nor assignment of an NDC number is a determination that a product is a drug as defined by the FD&C Act, *nor does either denote that a product is covered or eligible for reimbursement by Medicare, Medicaid or other payers*.

National Drug Code Directory, available at:

http://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm (emphasis added).

A directory is not an "administrative report." Merriam-Webster's Dictionary defines a directory as "a book or collection of directions, rules, or ordinances" or "an alphabetical or classified list (as of names and addresses)." Just as a telephone directory, for example, cannot be termed an "administrative report" under the FCA, neither may the NDC Directory.

Next, Defendants cite Federal Register Notices of Opportunity for Hearing (NOOH) as disclosures of the DESI status of various drug products. Notably, though, Defendants do not point to one NOOH out of the hundreds in existence that identifies any drug contained in the Complaint, or any Defendant named in the Complaint. The Relator's claims do not rest solely on Defendants' misrepresentations to CMS of their Medicaid ineligible DESI 5 drugs as having Medicaid eligible DESI 2 status, however. Defendants' drugs cannot meet *any* aspect of the Covered Outpatient Drug definition contained in 42 U.S.C. §1396r-8(k)(2)(A)(i)-(iii), as Relator alleges in her Complaint.

FDA approval, of course (subsection (i)), is one way to meet the definition. Defendants' drugs fail on this score. Subsection (ii) provides another: a drug sold in the United States before 1962, or one identical, related, or similar (IRS) to it, as to which the FDA has not made a final determination that it is a "New Drug." This subsection, however, does not encompass DESI drugs. They are relegated to subsection (iii), which expressly concerns DESI drugs, those "described in §107(c)(3) of the Drug Amendments of 1962." A DESI drug may only qualify as a Covered Outpatient Drug "if it is described in §107(c)(3) … and the FDA has determined there is a "compelling justification for its

medical need." 42 U.S.C. §1396r-8(k)(2)(A)(iii). None of the Defendants' DESI drugs have been determined to meet this "medical need" exception. [11]

The Final FDA Compliance Guide (2006) and its predecessors have no bearing on the claims raised here. The Guide does not mention any of the Defendants, their products, Medicaid, the Medicaid Rebate Programs, or Covered Outpatient Drugs. At most, it acknowledges the obvious, that certain drug marketers take advantage of the government's lack of enforcement resources and sell unapproved drugs. A government publication that generally states common knowledge does not give rise to the public disclosure bar. *See, e.g., United States ex rel. Ven-A-Care v. Actavis Mid Atl. LLC,* 659 F. Supp. 2d 262, 267-68 (D. Mass. 2009). *See also, United States ex rel. Baltazar v. Warden*, 635 F.3d 866, 868 (7th Cir. 2011)("As far as we can tell, no court of appeals supports the view that a report documenting widespread false claims, but not attributing them to anyone in particular, blocks *qui tam* litigation against every member of the entire industry.")

3. There Is No Evidence That The Government Had Already Formulated The Same Theory.

Defendants allege that public disclosures also establish the United States had already formulated a theory substantially similar to Ms. Conrad's prior to the filing of the complaint. Def. Mem. at 22. In support, Defendants refer to FDA Compliance Policy Guides (*id.*, at 23) which advise generally that drugs may not be lawfully marketed

[11] This analysis demonstrates that Defendants' attempt to shoehorn their DESI drugs into subsection (ii) is incorrect because it violates the plain language of the statute, which addresses them in subsection (iii). But there is another reason subsection (ii) cannot apply to Defendants' drugs. The FDA has deemed all drugs subject to DESI review as "New Drugs," precluding application of the Covered Outpatient Drug definition of subsection (ii) to them for this reason as well.

unless they are FDA approved, as the Guide indicated FDA's belief that "it is not likely that any currently marketed prescription drug product is grandfathered or is otherwise not a new drug." 2006 Compliance Guidance, at 12.

Defendants' argument on this score is fundamentally flawed. First, the Compliance Policy Guide merely states that there are thousands of unapproved, illegal drugs on the market, but the FDA, due to limited resources, had to exercise enforcement priorities as to these products.[12] What's more, the information contained in the Guide does not comprise even one of the factual elements of liability in this case. And as above, general information about widespread compliance issues in an industry, like this Guide, do not trigger the public disclosure bar. *See United States ex rel. Cooper v. Blue Cross and Blue Shield of Fla., Inc.*, 19 F.3d 562, 566 (11th Cir. 1994).

II. But For Defendants' Knowing Inclusion Of Ineligible Products In Their CMS Submissions, States Would Not Have Sought And Obtained Millions of Dollars In Medicaid Reimbursement For Ineligible Products: Causation, Scienter And Materiality Are Sufficiently Alleged.

Defendants' argument that the Complaint fails to plead falsity, scienter and materiality as to Non-Drugs, supposed state approved products, and DESI 5 drugs that FDA delayed bringing enforcement measures against, Def. Mem. at 27-38, is based on a misunderstanding of the law, and the allegations contained in the Complaint itself. There is no authority for the proposition that the federal government can reimburse the states for these products.

[12] The 2003 Proposed FDA Compliance Policy Guide was issued *after* Relator filed her lawsuit.

A. A State's Choice To Provide Coverage For Products That Are Not Covered Outpatient Drugs Does Not Entitle The State To Medicaid Reimbursement For Those Products.

Under the Medicaid Rebate Program, only products that meet the definition of Covered Outpatient Drugs are eligible for federal reimbursement, and then only if the drug's manufacturer enters into an agreement with the Secretary of the Department of Health and Human Services to make a specified rebate. 42 U.S.C. §§ 1396r-8(c)(1), (2). Defendants have represented dietary supplements, which are not drugs, as Covered Outpatient Drugs so that states would unwittingly pay for them and seek federal Medicaid reimbursement.

Defendants misstate the law when they claim that the states are entitled to federal Medicaid reimbursement for vitamins, minerals, and other Non-Drug products. Def. Mem. at 27, 30. State Medicaid plans can cover whatever they wish, but a state's choice to pay, e.g., for non-prescription vitamin C because it views it as a healthy dietary supplement neither converts vitamin C to a Covered Outpatient Drug nor in any way entitles the state to federal Medicaid reimbursement for its choice to pay for it.

A 1997 Medicaid Drug Rebate Program Release makes clear that non-prescription vitamins and Non-Drugs are not Covered Outpatient Drugs:

> VITAMINS AND NON-DRUG PRODUCTS
>
> As a general rule, only those vitamins that are prescription vitamins meet the definition of a covered outpatient drug, as defined at section 1927(k)(2)(A) of the Social Security Act (the Act). The Food and Drug Administration (FDA) staff have informed us that only prescription vitamins should be assigned National Drug Codes (NDCs). Generally, *nonprescription vitamins are considered dietary food supplements, not drugs, and should not have NDCs assigned to them*. Based on the FDA's criteria and the definition of a covered outpatient

> drug, over-the-counter (OTC) vitamins would not be considered covered outpatient drugs. (Emphasis supplied.)

Medicaid Drug Rebate Program Release No. 30 (1997).

Defendants cite 42 U.S.C. § 1396a(a)(2)(requiring that a state plan for medical assistance provide for a certain level of state financial support) and § 1396b (providing for the amount of federal payments to the states) for the proposition that state programs are entitled to reimbursement from the federal government for these Non-Drug products, if the state elects to cover them. Def. Mem. at 27, 30. Neither of these statutory provisions, however, support the Defendants' claims, or make any reference to federal reimbursement to the states for non-drug products.[13] Defendants also assert that "certain Non-Drug products are actually considered 'Covered Outpatient Drugs' based on the States' coverage election." Def. Mem. at 28. This is simply untrue and, unsurprisingly, Defendants fail to cite any authority for such a proposition.

In support of their argument, Defendants refer to state drug lists from five states for various years between 2002 and 2006. But that these lists contain Non-Drug products (or illegal drugs or DESI 5 drugs for that matter) does not establish that they are Covered Outpatient Drugs eligible for federal reimbursement. The Relator does not dispute that the states *believed* that these products were Covered Outpatient Drugs – in fact that is the basis for her FCA claims: that Defendants' false statements resulted in the inclusion of their ineligible products on the CMS drug list, also known as the MDRI list,

[13] Defendants also contend that states are permitted to cover Non-Drug products, such as liquid meal replacements, as "medical supplies" pursuant to the Medicaid home health care services benefit. *See* Def. Mem. at 28. But among other distinctions, none of the products contained in the Complaint are "medical supplies" or liquid food.

which caused states to unwittingly pay for them believing they were covered and submit claims for federal reimbursement. The states believed they were covered because the Defendants represented that they were.

If a state chose to cover a product with its own funds, that payment is outside the scope of this *qui tam,* which targets only federal Medicaid payments for ineligible drugs and Non-Drugs. If Defendants are suggesting that the states are entitled to federal reimbursement through some other mechanism than the Medicaid Rebate Program, they have not identified what that mechanism is, what the requirements for reimbursement are, or what amount is reimbursable. The law is clear that there can be no federal reimbursement by the Medicaid Rebate Program for drugs that do not meet the definition of a Covered Outpatient Drug.

That Defendants' non-covered products were paid for by the states and reimbursed by the Medicaid Rebate Program is the basis for this *qui tam.* But for the Defendants' submission of false records and statements to the Medicaid Rebate Program, the Non-Drugs included in this case would never have been listed as Covered Outpatient Drugs, states never would have paid for them as Covered Outpatient Drugs,[14] and the federal government would never have paid states their federal share. In short, Defendants violated the FCA by misrepresenting their products as Covered Outpatient Drugs, causing the Non-Drug products to *appear* to be eligible for federal Medicaid reimbursement, and resulting in hundreds of millions of dollars in damages

[14] At all material times, the overwhelming majority of the state pharmacy plans provided explicitly that the states will not cover a pharmaceutical product unless it meets the definition of a Covered Outpatient Drug.

to the federal government. Causation, scienter and materiality are thus sufficiently alleged.

Finally, Defendants fail to refute Relator's alternate basis for Non-Drug liability, that the Non-Drug products at issue in the Complaint could never meet the definition of a Covered Outpatient Drug because an NDC is not required for Non-Drugs. For a product to qualify as a Covered Outpatient Drug, it must be the type for which an NDC is required by the FDA:

> (3) Limiting definition
> The term "covered outpatient drug"... "does not include any such drug product for which a National Drug Code Number is not required by the Food and Drug Administration ... [or] used for a medical indication which is not a medically accepted indication."

42 U.S.C. § 1396r-8(k)(3).

There is no requirement that Non-Drugs have an NDC number, and, in fact, the opposite is true: affixing an NDC number to a Non-Drug is misbranding.[15] Defendants are liable for all of the payments for Non-Drug products in Relator's Complaint on this basis alone.

B. Relator Makes No Claims Concerning OTC Drugs, And Demonstrates Both Falsity And Scienter With Respect To Non-Drugs.

Defendants next argue that OTC drugs can be Covered Outpatient Drugs, and that therefore Ms. Conrad cannot plead falsity or scienter as to these products. Def. Mem. at 32. Relator agrees that OTC drugs prescribed by a physician are Medicaid

[15] FDA has cited manufacturers for distributing misbranded products "because the labels bear NDC numbers but the products are not registered with FDA as drugs..." *See* July 31, 2001 Warning Letter, #2001-NOL-41, to PharmaScience Laboratories, LLC.

eligible, and the Complaint does not allege otherwise. To the extent Defendants equate OTC *supplements* (Non-Drugs) with OTC *drugs*, they mischaracterize the Complaint. Ms. Conrad's claims concerning OTC products are limited to those that are not drugs.

As above, the entire Complaint pleads falsity with regard to Non-Drugs: (1) falsity of Defendants' representations to CMS in their Medicaid Rebate Agreements and quarterly submissions; and (2) falsity of the pharmaceutical claims themselves, because the Non-Drugs failed to meet the definition of a Covered Outpatient Drug and therefore were non-covered false claims. The Complaint pleads *scienter* with regard to Non-Drugs, including at ¶¶ 4(iii), 8, 9, 11, 123, and 125.

In attempting to refute Relator's falsity and *scienter* allegations, Defendants make irrelevant claims about OTC "drugs," asserting that OTC drugs "may also qualify as 'Covered Outpatient Drugs' — even without FDA drug approval — if states exercise their authority to include such products within their state plan for medical assistance, 42 U.S.C. § 1396r- 8(k)(4); *id*. § 1396d(a)(12)." Def. Mem. at 32. Again, Relator has never asserted that an OTC *drug* is not a Covered Outpatient Drug. Dietary supplements and non-prescription vitamins, however, are not *drugs* and therefore cannot be Covered Outpatient Drugs.[16] Defendants know this.

Under Defendants' logic, the alleged state coverage election obviates causation, intent, and *scienter*, which, as just demonstrated, is not the case. Even if Defendants were correct – and they are not – Defendants would need to show the following for each

[16] See also the various definitions of Covered Outpatient Drugs at 42 U.S.C. 1396r-8 (K)(7), which demonstrates that Defendants' argument that a Non-Drug can be a Covered Outpatient *Drug*, is an oxymoron.

product Relator has named: that every state covered each product *outside of the Medicaid Rebate Program*, and not because of the drug's inclusion on the Medicaid drug list; that federal reimbursement is authorized for such drugs, in equivalent amount to the claims at issue here; and that the federal government, for each product, would have provided its federal share for such product regardless of whether it met the definition of a Covered Outpatient Drug. Defendants have not done this for even one product, and cannot do so.

C. Products Subject To DESI Review Cannot Be Legally Marketed Until They Receive Approved NDAs Or ANDAs - Approvals Defendants' Products Lacked And As Such Can Not Be Covered Outpatient Drugs.

Defendants argue that for Conrad's claims to survive a motion to dismiss, it must not be plausible that the drugs in question were properly classified as DESI Code 5 when the claims were submitted. Def. Mem. at 34. Defendants' argument on this score is misplaced because *none* of the "DESI products" listed in the complaint could ever qualify as a Covered Outpatient Drug. Under the statutory definition, a DESI product could only qualify as a Covered Outpatient Drug if "the Secretary has determined there is a compelling justification for its need." 42 U.S.C. § 1396r-8(k)(2)(A)(iii). Defendants' drugs cannot fit in this category because no product in this lawsuit is one for which the Secretary has found a compelling medical need. This alone is dispositive with respect to liability concerning the DESI drugs in this case.

In addition, the Complaint's allegations regarding the false DESI 2 Code that Defendants submitted to CMS demonstrate Defendants' scheme, but they are not the

sole reason that misrepresented "cough-cold" products are not Covered Outpatient Drugs. As stated in paragraph 52 of the Complaint:

> The following paragraphs describe three categories of Illegal Drugs billed to and paid for by Medicaid as a result of the conduct described herein: (1) Unapproved "New Drugs"; (2) DESI LTE's; and (3) Levothyroxine products. These categories are not mutually exclusive. In fact, *often an Illegal Drug will fit into more than one category, and will be excluded from Medicaid eligibility for more than one reason.* Although described separately, all have in common that they are not Covered Outpatient Drugs, despite being passed off as such by the Defendants. This deception is the fundamental basis of liability for all of the Defendants' products, no matter what category they occupy.

As previously noted, by arguing that select DESI drugs in this case are IRS to pre-1962 drugs, Defendants vainly attempt to fit their products into subsection (ii) of the Covered Outpatient Drug definition. 42 U.S.C. § 1396r-8(k)(2)(A)(ii)(drugs sold before 1962, or IRS to such drugs, and not subject to a final determination by the FDA that they are "New Drugs"). DESI drugs can never meet the requirements of subsection (ii) of the definition because the FDA has repeatedly stated that "[a]ll drugs covered by the DESI review are 'new drugs' under the [FD&C] Act."[17] Subsection (iii) provides the only possibility for DESI drugs to be considered Covered Outpatient Drugs –the rare

[17] *See e.g. Carbinoxamine Products; Enforcement Action Dates,* 71 Fed. Reg. 33462, 33463 (June 9, 2006); *Oral Prescription Drugs Offered for Relief of Symptoms of Cough, Cold, or Allergy; Drug Efficacy Study Implementation,* 76 Fed. Reg. 11790 (March 3, 2011); *Unapproved and Misbranded Oral Drugs Labeled for Prescription Use and Offered for Relief of Symptoms of Cold, Cough, or Allergy,* 76 Fed. Reg. 11794 (March 3, 2011).

circumstance, not present here, where the Secretary of HHS has found that they meet a compelling medical need. [18]

Even documents Defendants point to in their Motion to Dismiss make clear that all so-called DESI drugs are New Drugs. In its Compliance Policy Guide 7132c.02 (CPG), the FDA first acknowledges in 1976 the presence of unapproved drugs on the market. The CPG "reaffirms that all products marketed as drugs under the DESI program are new drugs, and therefore, require an approved NDA or ANDA for marketing." CPG 7132c.02 § 440.100 at 134.

D. Extended Release Products Containing Guaifenesin and Hydrocodone Were Never Covered Outpatient Drugs, And The FDA Has Taken Recent Action To Rid The Market Of These Illegal Products.

Defendants are simply incorrect in their suggestion that the FDA's delay in ridding the market of illegal Guaifenesin and Hydrocodone products constituted a "grace period" that made these illegally marketed drugs Medicaid eligible. Def. Mem. at 36 – 38.

[18] Defendants' reference to the Weiss List as support for their claim that their products are approved is not helpful. The Weiss list is an unofficial categorization of drugs that FDA employees compiled at a given time. It is not determinative of the legal status of the "cough-cold" drugs in this lawsuit – only FDA official action is – and, as noted, none of these drugs meets the requirement of having an approved NDA or ANDA. Finally, Appendix C to Defendants' brief is not the "Weiss List" – it is Defendants' unilateral view of how the illegal drugs in this lawsuit fit into the "Weiss List" – hardly determinative, and not even appropriate for consideration. Defendants' contention that select drugs are identical, related, or similar (IRS) to pre-1962 drugs is a question of fact. Even if the "Weiss List" were conclusive, Defendants' determinations that their drugs are IRS to certain drugs on the "Weiss List" (which is irrelevant to a drug's true DESI status), are not for them to make. IRS status, to the extent relevant here, is a question of fact and law, which would then need to be addressed for each drug named in this lawsuit.

FDA inaction is irrelevant. How long it took the FDA to get illegal drugs off the market has no bearing on their Medicaid eligibility. These products were *always* illegal and as such could never meet the definition of a Covered Outpatient Drug. The FDA ultimately did take enforcement action in 2007, reinforcing Relator's claims and perhaps took action precisely *because* of Relator's claims. *See Drug Products Containing Hydrocodone; Enforcement Action Dates,* 72 FR 55780 (October 1, 2007)*; Timed-Release Drug Products Containing Guaifenesin; Enforcement Action Dates,* 72 FR 29517 (May 29, 2007).

Contrary to Defendants' argument, Relator has sufficiently pled causation. *See, e.g.,* Complaint ¶¶ 112, 121, 123-127.

III. The Allegations Of The Tenth Amended Complaint Meet All Applicable Requirements As To Specificity.

Rule 9(b) requires that "[i]n alleging fraud or mistake, a party must state with particularity the *circumstances* constituting fraud or mistake." Fed. R. Civ. P. 9(b) (emphasis added). The Relator has done so in this case with more than enough specificity, as to both her claims under Section 3729(a)(1)(A) (knowingly presenting a false claim, or causing a false claim to be presented), and Section 3729(a)(1)(B) (knowingly making a false record or statement material to a false claim, or causing a false record or statement to be made).

The False Claims Act prohibits both directly presenting a false claim, and indirectly causing a false claim to be presented by a third party. Just as there is a distinction between these direct and indirect false claims, the First Circuit distinguishes between the nature of the particulars that must be pled to satisfy Rule 9(b) in these

differing circumstances. In indirect, or "inducement" cases, the relator need not provide details as to each false claim to satisfy Rule 9(b), but can instead meet the Rule's requirements by providing "factual or statistical evidence to strengthen the inference of fraud beyond possibility." *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 733 (1st Cir. 2007); *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 29 (1st Cir. 2009); *Cf. United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220 (1st Cir. 2004)(case involving allegation of direct presentment of false claim required factual detail as to challenged claims).

Although Ms. Conrad's case involves indirect claims, the Defendants fault her for not meeting the inapplicable direct claim standard.

A. The *Karvelas* Standard Defendants Cite Is Inapplicable.

In arguing that the Complaint fails to meet the standards of Rule 9(b), Defendants ignore relevant First Circuit case law regarding the pleading standards in cases like this one, alleging Defendants induced *third parties* to file false claims. Instead the Defendants rely, wrongly, on *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220 (1st Cir. 2004), which involves the stricter standard applicable to cases alleging that the defendants themselves submitted false claims.

In *Karvelas*, unlike here, the relator alleged that the defendants themselves "knowingly filed improper claims." *Id.,* at 233-234. The relator's failure to set forth specific details as to the claims was fatal. *Id.* (citing conclusory allegations such as "staffing numbers in the Medicaid and Medicare filings were make believe throughout the entire hospital."). *Karvelas* simply did not address the appropriate standard in an

indirect case. In fact, contrary to Defendants' suggestion, *Karvelas* did not even create a blanket pleading rule mandating requirements for all *direct* cases. Rather, the Court emphasized that its holding is limited to the facts of the case noting that it did not "constitute a checklist of mandatory requirements that must be satisfied by each allegation included in a complaint." *Id.,* at 233.

B. The Complaint Meets The Standard Articulated In *Rost* And *Duxbury* For Indirect Or "Inducement" Cases: It Provides Factual Evidence To Strengthen The Inference Of Fraud Beyond Possibility.

1. The Applicable Standard.

The standard applicable to cases alleging the defendant induced third parties to file false claims was articulated by the First Circuit in *Rost* and *Duxbury* and the cases that follow. *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 733 (1st Cir. 2007)); *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 29 (1st Cir. 2009). In *Rost* the First Circuit recognized "a distinction between a *qui tam* action alleging that the defendant made false claims to the government, and a *qui tam* action in which the defendant induced *third parties* to file false claims with the government." *Rost,* 507 F.3d at 732. In an "inducement" case, the relator need not provide details as to each false claim to satisfy Rule 9(b), but can instead meet the Rule's requirements by providing "factual or statistical evidence to strengthen the inference of fraud beyond possibility." *Duxbury,* 579 F.3d at 29; *Rost,* 507 F.3d at 733; *see also United States ex rel. Grubbs v. Kanneganti,* 565 F.3d 180, 190 (5th Cir. 2009)(FCA claims may survive under Rule 9(b) "by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted").

Here, that standard is met. The factual evidence of fraud is clearly alleged in the Complaint: the Defendants falsely represented to the government that their products were Covered Outpatient Drugs, and the government paid claims for these non-Covered Outpatient Drugs. Absent fraud, this would not have happened. The inference of fraud is much stronger than a mere possibility, satisfying the *Rost* and *Duxbury* standard.

Since the Court's 2009 decision in *Duxbury*, several district courts in this Circuit have denied similar motions to dismiss under Rule 9(b) in indirect cases. In *United States ex rel. Lisitza v. Johnson & Johnson, Ortho-McNeil-Janssen Pharmaceuticals, Inc.*, 765 F. Supp. 2d 112 (D. Mass. 2011), the relator alleged violations of the Anti-Kickback Statute caused a third-party to file false claims for Medicaid reimbursement. Because the false claims were filed by a third party, precise details as to each false claim were not required. *Id.*, at 129. The complaint was sufficient because it specified "the relevant time period ... the manner in which the kickbacks were paid ... and the claims alleged to be false that flowed from the various kickback schemes," and contained illustrative documents, such as applicable contracts. *Id.* In another similar recent case, the requirements of Rule 9(b) were satisfied because "although Relator [could not] identify each particular instance of a knowingly false certification, the Complaint as a whole [was] sufficiently particular to strengthen the inference of fraud beyond possibility."

United States ex rel. Westmoreland v. Amgen, Inc., 738 F. Supp. 2d 267, 276 (D. Mass. 2010).[20]

2. The Relator's Specific Allegations.

In the eighty-two page Tenth Amended Complaint, Relator alleges that each Defendant falsely represented to CMS that certain specifically identified products were Covered Outpatient Drugs eligible for Medicaid reimbursement, which caused the states to pay for them and seek reimbursement from CMS, and caused CMS to pay the false claims. Tenth Amended Complaint, ¶¶ 2-3. The incentive is clear: falsely claiming Medicaid reimbursement eligibility guaranteed the Defendants access to the $70 billion Medicaid market. *Id.*, ¶ 29. Relator's allegations include the following specific facts and allegations regarding the fraudulent conduct:

> • each Defendant signed the applicable Drug Rebate Agreement (a standard form of which was attached to the Tenth Amended Complaint as Exhibit B), which required Defendants to truthfully represent the eligibility of their drugs for reimbursement, to identify all Covered Outpatient Drugs (Drug Rebate Agreement, p. 5), to update their representations of reimbursement eligibility quarterly, and to abide by all laws, regulations and procedures applicable to Medicaid, including reimbursement (*id.*, ¶¶ 27, 37);
>
> • the specific date of each respective Defendant's initial, underlying misrepresentation - the date it entered into its Medicaid Drug Rebate Agreement based on the misrepresentation that its products were Covered Outpatient Drugs - and the continuation of such misrepresentations through the required quarterly reports (*id.*, ¶¶ 36-38, 41-42, 49);

[20] Even before *Duxbury*, allegations such as those in the Tenth Amended Complaint were sufficient for purposes of Rule 9(b). For example, in *Simonet v. SmithKline Beecham Corp.*, 506 F. Supp. 2d 77, 90 (D.P.R. 2007), the court recognized that the allegations must place the defendant "on sufficient notice of the alleged misrepresentation and concealment such that [it] can defend against the underlying charge," and that allegations of the nature, location and time period of the drug company's false representations satisfy that standard.

• the fraudulent activity, to wit, their representation that the products met the definition of a Covered Outpatient Drug and therefore were eligible for Medicaid reimbursement when, in fact, they were not (*id.*, ¶¶ 2, 6, 8, 10, 11, 28, 51, 52, 76, 84, 92, 107, 121, 123, 124)[21];

• the fact that the Defendants knowingly represented that each identified product was a Covered Outpatient Drug, despite the fact that none of the products identified in the Tenth Amended Complaint were Covered Outpatient Drugs as required for reimbursement under the Rebate Agreement (*id.*, ¶¶ 4, 22, 41, 123)[22];

• for each respective Defendant, the identity of each specific drug, the unapproved product's name, the NDC number and the amounts paid by Medicaid and other information specific to the illegal drug (*id.*, ¶¶ 55-111);

• for each respective Defendant, the identity of each non-prescription vitamin, mineral or dietary supplement ("Non-Drug"), the Non-Drug's name, the NDC number and the amounts paid by Medicaid (*id.*, ¶ 128);

• that in reliance on Defendants' false representations that their drugs were Covered Outpatient Drugs, CMS informed the states to use the information containing the false Covered Outpatient Drug numbers to determine reimbursement eligibility through the Federal Financial Participation ("FFP") program (*id.*, ¶¶ 45-50, 125); and

• the false claims resulting from the Defendants' fraudulent scheme: as a result of the Defendants' misrepresentations, the states paid for ineligible products and submitted reimbursement claims to the federal government, which paid the states' quarterly claims (*id.*, ¶ 5, 6, 50).

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[21] Paragraph 49 inadvertently referred to ¶ 38 for the initial dates of fraudulent representations; the reference should have been to ¶ 36.

[22] Defendants argue that the Relator has failed to plead knowledge with sufficient particularity. Def. Mem. at 41-42. On the contrary, the above-referenced allegations satisfy the standard that "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." *See, e.g., United States ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163, 1171 (10th Cir. 2010); *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 185 (5th Cir. 2009); *United States ex rel. Williams v. Martin-Baker Aircraft Co.*, 389 F.3d 1251, 1256 (D.C. Cir. 2004).

In light of the First Circuit's *Duxbury* and *Rost* decisions, the Tenth Amended Complaint more than satisfies all applicable standards of pleading.

C. The Relator's Allegations As To Section 3729(a)(1)(B) (False Statements) Are Sufficient.

Similarly, Defendants' contention that the Complaint lacks the specificity required of claims under §3729(a)(1)(B) (false statements material to a false claim) fails. Together, the allegations that certain products were not Covered Outpatient Drugs, not eligible for Medicaid reimbursement, coupled with the allegation that claims for these drugs were actually paid necessarily implies establishes that a false statement was made. *See United States ex rel. Branch Consultants, L.L.C. v. Allstate Ins. Co., et al.*, 668 F. Supp. 2d 780, 810 (E.D. La. 2009). As in *Branch Consultants*, it takes a very short step "to make the reasonable inference…that a record was made to support these claims." *Id.* Certainly, the government would not have paid the claims related to these drugs without a record ever having been made. This situation is "vastly different from one in which a plaintiff simply posits…the existence of a statement or record." *Id.* Where, as here, the relator has "provided considerable factual details that simply cannot be true without the existence of a statement or record having been made by defendants," then the pleadings are sufficiently particular under §3729(a)(1)(B). *Id.*

All of the requirements of specificity have been satisfied: the Relator alleges the "who" (as a result of each Defendants' misrepresentations, states and providers submitted false claims for reimbursement which were paid); the "what" (the Defendants' representations that their products were Covered Outpatient Drugs, with

each product specifically identified in the Tenth Amended Complaint); the where (the misrepresentations in the Defendants' submissions to the CMS claiming Covered Outpatient Drug status); and the "when" (the exact date of the initial misrepresentation and its continuation quarterly from that date). As in *Lisitza*, 765 F. Supp. 2d 112, Relator sufficiently alleges the "relevant time period," the "manner" of the scheme and the resulting false claims, and, as in *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 751 F. Supp. 2d 277, 290 (D. Mass. 2010), Relator sufficiently alleges the "time and place of the fraudulent representations ... identities of the perpetrators and recipients and ... content of the misrepresentations" and causation.

Relator is not required to identify each instance of a false certification. The Tenth Amended Complaint as a whole is "sufficiently particular to strengthen the inference of fraud beyond possibility." *Westmoreland*, 738 F. Supp. 2d at 276. The allegations strongly support more than such an "inference" and, therefore, the motion to dismiss should be denied.

IV. The Operative FCA Liability Provisions Were Unchanged By The 2009 Amendments; Any Inadvertent Misidentification Of The Version In Effect Is A Nonsubstantive Clerical Error.

In her initial Complaint filed in 2002, and through multiple amendments, Ms. Conrad asserted claims under the FCA liability provisions in effect in 2002, 31 U.S.C. § 3729(a)(1) and (2). This section was amended in 2009, but the amendment made no substantive changes to the operative provisions relied on by the Relator. Specifically, the provisions in effect in 2002 provided:

(a) Liability for certain acts.--Any person who—

> **(1**) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;
>
> **(2)** knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;

is liable to the United States Government. 31 U.S.C. §3729(a)(1) and (2)(eff. 1994).

The amended version that became effective in 2009 provides:

> **(a)** Liability for certain acts.--
>
> **(1)** In general**.**--Subject to paragraph (2), any person who--
>
> > **(A)** knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
> >
> > **(B)** knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

is liable to the United States Government. 31 U.S.C. 3729(a)(1)(A) and (B) (eff. 2009).

In all material respects, the provisions are the same. Both impose liability for presenting or causing to be presented a false claim for payment or approval, and for knowingly making a false record or statement to get a false claim paid. The prior enactment included the proviso that the false claim be presented to a government employee, and that the false statement be made to get a claim paid by the government. The later provision omits the "government" language. Because the allegations in this case are that the false statements and false claims were submitted to CMS, an agency of the federal government, this change is immaterial.

Elevating form over substance, Defendants argue that the Relator's claims must be dismissed because of her references to the amended but substantially identical provision, even though the prior enactment is in fact cited in the body of the Tenth

Amended Complaint. See Complaint, ¶ 20. See also ¶ 12, and 140(a) (referring to Section 3729). As the references to the 2009 version are obviously clerical errors, Defendants' motion to dismiss on this ground should be denied.

V. The Relator's Claims Relate Back To The Original Filing.

A. The Operative Date For Statute Of Limitations Purposes Is The *Filing* Of the Complaint, Not The Unsealing.

Ms. Conrad asserts claims beginning six years prior to the filing of the initial Complaint in 2002, in accordance with the FCA's six year statute of limitations. 31 U.S.C. 3731(b)(1). Defendants seek to dismiss claims that arose more than six years before the *unsealing* of the Complaint, in 2010. Relying on *United States v. Baylor Univ. Med. Ctr.,* 469 F.3d 263 (2nd Cir. 2006), Defendants argue that the FCA statute of limitations begins to run from the day a complaint naming a particular defendant is *unsealed*, rather than from the date the action is commenced, and that relation back under Rule 15(c) or tolling under the FCA does not apply. Def. Mem. at 44-46. But *Baylor* (1) did not address the circumstances present in this case, and (2) has been soundly rejected by courts in jurisdictions across the country, including this one.[23] The statute of limitations begins to run from the date the case is brought, not the date it is unsealed. *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Actavis Mid Atlantic, LLC*, 659 F. Supp. 2d 262, 273 (D. Mass. 2009).

[23] *See, e.g., United States ex rel. Serrano v. Oaks Diagnostics, Inc.*, 568 F. Supp. 2d 1136, 1139 (C.D. Cal. 2008)(specifically refusing to follow *Baylor*, and citing *Rost,* 446 F. Supp. 2d 6; *United States ex rel. Miller v. Bill Harbert Int'l Contr., Inc.,* 2007 WL 851855, 2007 U.S. Dist. LEXIS 17658 (D.D.C. Mar. 14, 2007): *United States ex rel. Cosens v. St. Francis Hosp.,* 241 F. Supp. 2d 223 (E.D.N.Y. 2002); *Miller v. Holzmann,* 563 F. Supp. 2d 54 (D.D.C. 2008) as illustrative examples.

Section 3731(b)(1) of the False Claims Act provides generally that civil actions may not be brought more than six years after the date of the violation. Rule 15(c)(1) provides that an amendment to a pleading relates back to the original pleading when:

> **(A)** the law that provides the applicable statute of limitations allows relation back; [or]
>
> **(B)** the amendment asserts a claim or defense that arose out of the conduct, transaction, or occurrence set out--or attempted to be set out--in the original pleading. Relation back is appropriate in this case under both provisions.

In *Ven-A-Care,* as here, the defendants argued that relation back under Fed. R. Civ. P. 15(c)(1)(A) did not apply to a sealed complaint. *Id.,* at 272. There, the original complaint was filed in 2000 and defendants challenged as time barred a 2008 amended complaint filed by the relator. *Id.* The court rejected the defendants' argument, holding that Rule 15(c)(1)(A) applied and that the claims related back to the initial filing against each defendant, not to the date of the unsealing. *Id.* As the court noted, it has already been established that an amended complaint filed by the government "relates back to the relator's original *qui tam* complaint." *Id.* (citing *In re Pharm. Indus. Average Wholesale Price Litig*., 498 F. Supp. 2d 389, 397–98 (D. Mass. 2007)). *See also* 31 U.S.C. §3731(c)(relation back provision of the FCA). Because a relator under the FCA is acting in the name of the government, there is no reason to apply a different rule when the amended complaint is filed by the relator. *Id.* Both relate back to the initial, sealed filing.

Nearly every court to consider this issue has taken the same approach as *Ven-A-Care,* finding that relation back applies for several reasons. First, the plain language of

the statute supports this rule. The FCA provides that the limitations period begins when the action is "brought," not when it is unsealed. *See* 31 U.S.C. § 3731(b); *United States ex rel. Downy v. Corning, Inc.,* 118 F. Supp. 2d 1160, 1171 (D.N.M. 2000)(under federal law, case is initiated, and the statute of limitations tolled, when the complaint is filed); *United States ex rel. Parikh v. Premra Blue Cross,* 2007 WL 1031724, *3 (W.D. Wash. 2007); *In re Pharm. Indus. Average Wholesale Price Litig.*, 498 F. Supp. 2d 389, 396 (D. Mass. 2007)(filing of complaint "suffices to satisfy statute of limitations" even if not immediately served; citing Fed. R. Civ. P. 3. regarding commencement of an action).

Next, the FCA expressly allows the government to seek extensions of the seal upon a showing that it is diligently investigating the case. 31 U.S.C. § 3730(c)(4). There is no limit in the statute as to the number of extensions the government can seek. Given this, it would be illogical to "limit claims when the government has sought [] and properly received those extensions" from the court. *Parikh,* at *3*; see also Ven-A-Care,* 659 F. Supp. 2d at 273 (delay in unsealing caused by government exercising lawful right to investigate; no evidence extensions were improper); *Downy*, 118 F. Supp. 2d at 1171. If claims could not relate back, each time the court granted a government extension request more potential false-claims recoveries would "recede behind the barrier of the continuously-moving limitations period." *Id.* If relation back were precluded, the relator could lose large swaths of claims because of government actions over which he or she has no control. *Id.*

The *Baylor* court addressed a different issue – whether the government's claims related back to the filing of the relator's complaint under Rule 15(c)(2), allowing relation

back when the government is added as a party as long as the defendant was on notice of the initial filing, or should have known. Obviously, this is not the issue raised here. There is no new party, and Rule 15(c)(1) does not require notice. *Baylor* acknowledged that relation back may be available in FCA cases under Fed. R. Civ. P. 15(c)(1)(allowing claim to relate back if the applicable statute permits it) because "there is a colorable argument that the FCA implicitly permits a form of relation back." *Baylor,* 469 F. 3d at 270; *see also United States of America ex rel. Miller v. Bill Harbert Int'l. Const., Inc.*, 608 F.3d 871, 879 (D.C. Cir. 2010)(§3731(c) of FCA "permits…relation back."). Finally, the *Baylor* court expressed concerns about the sufficiency of the initial complaint, which was far less specific than the Tenth Amended Complaint. The court recognized that even if Fed. R. Civ. P. 15(c)(1) and 31 U.S.C. § 3731 created a separate relation-back doctrine, the *Baylor* complaint may not have been "sufficient to commence the action for statute-of-limitations purposes." *Id.*

Relation back is appropriate here under Rule 15(c)(1)(B) as well, because the claims arise out of the same conduct set out in the original pleading. *See Bill Harbert Int'l. Const., Inc.*, 608 F.3d at 879 (both FCA and Rule Fed. R. Civ. P. 15(c)(1)(B) allow relation back "to the extent that the claim of the Government arises out of the conduct, transactions, or occurrences set forth, or attempted to be set forth, in the prior complaint"); *see also Ven-A-Care,* 659 F. Supp. 2d at 272 (amended complaint relates back to complaint in which allegations were first made). Here, the claims against each Defendant all arise from the same conduct, submitting false representations that their products were Covered Outpatient Drugs, when they were not. The fraudulent scheme

alleged in the Complaint is identical as to all drugs and Non-Drugs. The statute of limitations must run as to each Defendant from the date of the complaint in which each Defendant is first named.

B. The Fact-Specific Analysis Of Limitations Periods And Relation Back Under Rule 15(c)(1) Is Inappropriate At This Stage Of The Litigation Since A Motion to Dismiss Is Evaluated Strictly On The Pleadings.

A motion to dismiss is an inappropriate forum for the fact-intensive analysis necessary to evaluate the statute of limitations and the relation back doctrine. To be successful, a motion to dismiss pursuant to Rule 12(b)(6) must establish, based strictly on the pleadings, that the plaintiff has failed "to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). While it is true that pleading a cause of action "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do," the Complaint (as discussed at length *supra*) fully comports with the heightened pleading requirements of Rule 9(b) and is sufficiently detailed to survive this motion to dismiss. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

Given this legal backdrop, the factual analysis necessary to evaluate the complex procedural history of this case is premature. In the First Circuit, when there is a factual dispute about the statute of limitations in a case involving issues like those involved in the present action, it should not be handled on a motion to dismiss, as "the application of the provision is better handled on a motion for summary judgment." *Ven-A-Care*, 659 F. Supp. 2d at 274.

Conclusion

For all the foregoing reasons Defendants' motion should be denied.

Date: February 29, 2012

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on February 29, 2012 this document, filed through the ECF system, will be sent electronically to the registered participants as identified on the Notice of Electronic File (NEF).

/s/ John Roddy
John Roddy